

Implementing Laboratory Quality Management Systems in Mozambique: The Becton Dickinson–US President’s Emergency Plan for AIDS Relief Public-Private Partnership Initiative

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Background. Mozambique’s ministry of health (MOH) recognized the need to establish a national laboratory quality assurance (NLQA) program to improve the reliability and accuracy of laboratory testing. The Becton Dickinson–US President’s Emergency Plan for AIDS Relief Public-Private Partnership (PPP) was used to garner MOH commitment and train a cadre of local auditors and managers to support sustainability and country ownership of a NLQA program.

Methods. From January 2011 to April 2012, the World Health Organization Regional Office for Africa Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) checklist and the Strengthening Laboratory Management Towards Accreditation (SLMTA) curriculum were used in 6 MOH laboratories. PPP volunteers provided training and mentorship to build the capacity of local auditors and program managers to promote institutionalization and sustainability of the program within the MOH.

Results. SLIPTA was launched in 6 MOH laboratories, and final audits demonstrated improvements across the 13 quality system essentials, compared with baseline. Training and mentorship of MOH staff by PPP volunteers resulted in 18 qualified auditors and 28 managers/quality officers capacitated to manage the improvement process in their laboratories.

Conclusions. SLIPTA helps laboratories improve the quality and reliability of their service even in the absence of full accreditation. Local capacity building ensures sustainability by creating country buy-in, reducing costs of audits, and institutionalizing program management.

Keywords. laboratory QMS; Mozambique; PEPFAR; public-private partnership; laboratory systems.

Mozambique is a resource-limited country along the southeastern coast of Africa with a population of 22 million people. Mozambique is organized into 3 regions, 11 provinces, and 128 districts. Healthcare is provided primarily through the public sector under the coordination of the Mozambique Ministry of Health (MOH). As a result of a 15-year civil war (1977–1992), the healthcare system was severely crippled because the infrastructure was destroyed and the workforce displaced. Since then, significant efforts have been made to rebuild the healthcare system and improve equitable access to quality healthcare. The clinical laboratory network in Mozambique includes nearly 300 laboratories organized into 4 tiers, ranging from health centers to national reference laboratories. Clinical laboratories are managed by the Central Laboratory Department of the MOH, which has oversight of the country’s public sector hospitals, laboratories and blood banks. The National Institute of Health is a semiautonomous unit within the MOH that houses the

country’s national public health reference laboratories. The National Institute of Health has the mandate to provide technical support and training to the laboratory network and to implement and manage the national laboratory quality assurance (NLQA) program. All laboratories in the country are guided by an overarching national laboratory policy adopted by the MOH in 2013, which declares that laboratories will systematically establish and maintain a quality management system to ensure the reliability and accuracy of laboratory test results [1]. While provision of quality-assured laboratory services is a requirement of all laboratories in the country according to the national laboratory policy, prior to 2010 no NLQA program existed.

In 2010, Mozambique was invited to participate in the public-private partnership (PPP) initiative between Becton Dickinson and the President’s Emergency Plan for AIDS Relief (PEPFAR) program. Initial discussions with the MOH led to the identification of a priority to establish a NLQA program and begin implementing stepwise laboratory quality improvement toward accreditation in the country’s national reference laboratories and central and provincial clinical laboratories. The initial priority of the PPP was to capacitate local MOH professionals to implement and manage the national program, an

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essential strategy to promote sustainability. The fundamental components of a laboratory quality assurance program include providing a functional and safe laboratory environment, providing trained and competent personnel, maintaining equipment, providing adequate supplies and reagents, testing appropriate specimens, internal monitoring of quality, accurate reporting, and external quality assessments [2]. These components are necessary to provide accurate and precise laboratory results for patient care, prevention, disease surveillance, and outbreak investigation [3–6]. The development and execution of functional laboratory services at each tier of healthcare provision, from primary health centers to central hospitals, are the very underpinnings to successful care and treatment programs and will be critical in addressing future infectious diseases and long-term chronic disease prevention and treatment [7, 8]. This report focuses on the role the PPP played during 2010–2012 to create a cadre of MOH auditors and NLQA program managers and presents data from the first cohort of 6 laboratories enrolled in the Mozambique NLQA program.

METHODS

The MOH Central Laboratory Department and the National Institute of Health established priorities for the PPP, ensured that priorities of PPP aligned with their draft national laboratory strategic plan, identified the number and location of laboratories to be targeted through this effort, sensitized hospital and laboratory directors to the purpose and scope of the PPP activities, identified individuals to be trained, and monitored results of activities. Becton Dickinson staff managed the PPP work plan document and developed selection criteria for PPP volunteers on the basis of local considerations, including expertise in quality management, Portuguese language skills, and interest and availability to train and mentor Mozambican laboratory staff. Under the PPP's mechanism, PPP program staff monitored the performance of PPP expert volunteers working in country and provided training materials. To support the development and introduction of the NLQA program, the PPP provided 3 Becton Dickinson volunteers with expertise and experience in laboratory quality management system (QMS) duties, auditing, and project management. Between 2010 and 2012, PPP volunteers made a total of 6 technical assistance visits, providing training in laboratory auditing, project management, and mentorship of MOH laboratorians engaged in implementing the NLQA program. The Centers for Disease Control and Prevention (CDC) Mozambique office provided overall coordination to ensure complementarity of PPP work and to avoid duplication of efforts with those of other laboratory partners working in country. The American Society for Clinical Pathology facilitated the purchase of PPP-funded supplies and provided services to support PPP activities in-country. Semiannual meetings were held with the MOH and other stakeholders to monitor work plan implementation and make necessary changes.

Results of technical assistance and training visits were always provided to the MOH in the form of trip reports and summary findings after each in-country activity.

The MOH adopted the Strengthening Laboratory Management Towards Accreditation (SLMTA) curriculum and the World Health Organization Regional Office for Africa (WHO AFRO) Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) checklist as tools for implementation of the Mozambique NLQA Program [9, 10]. The WHO AFRO checklist comprises >250 questions and a scoring system with 258 points, using a 0–5-star rating. For each question in the checklist that is answered “yes,” 1–5 points are assigned. For questions partially answered “yes,” one point is assigned. No points are assigned to “no” answers. Laboratories will receive a recognition of 5 stars for achieving 244–258 points ($\geq 95\%$), 4 stars for 218–243 points (85%–94%), 3 stars for 192–217 points (75%–84%), 2 stars for 166–191 points (65%–74%), 1 star for 143–165 points (55%–65%), and no stars for scores of <143 points (<55%). Star ratings do not imply accreditation but demonstrate a laboratory's progress toward full compliance with the SLIPTA checklist across all 13 quality system essentials. The SLMTA curriculum, a task-based curriculum designed to teach laboratorians the tasks required to implement a quality management system at the facility level, was used during the 3 SLMTA workshops.

In an effort to build local capacity, the PPP focused on auditor training for MOH laboratory staff. Training focused on the International Organization for Standardization (ISO) 15 189, interpretation of the SLIPTA checklist, skills needed to interact with laboratory staff and management during the audit, and communication of results in oral and written form. Trainees were selected by the MOH, and criteria included: (1) ≥ 3 years of laboratory bench experience; (2) basic knowledge of quality assurance principles; (3) leadership role in the laboratory, such as a manager, unit, or section head; and (4) an interest in contributing to the NLQA program goals.

PPP volunteers also provided project management training to MOH staff engaged in managing the NLQA program. Twenty-eight trainees participated, including, national laboratory quality unit staff, laboratory managers, and quality managers.

Six laboratories were selected by the MOH to participate in the first round of the NLQA program: 2 central hospital laboratories in Beira and Nampula and 4 national reference laboratories (ie, microbiology, serology, immunology, and tuberculosis). Initial baseline audits were conducted in January 2011 by newly trained MOH auditors and side by side with PPP volunteer expert auditors. Five laboratorians from each enrolled laboratory, including the laboratory manager, quality manager, and section heads, were selected to participate in 3 SLMTA workshops, which took place over 13 months (Figure 1). Baseline audits were conducted prior to the first workshop, and results from each laboratory were presented at the first SLMTA

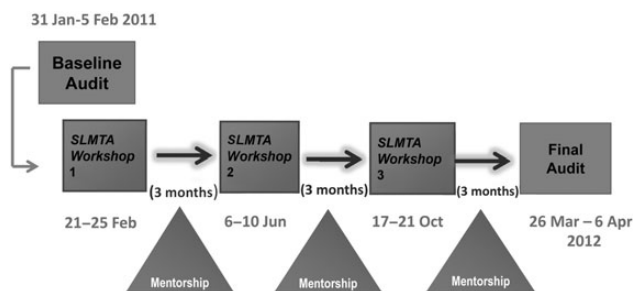


Figure 1. Timeline for implementation of the first round of the Strengthening Laboratory Management Towards Accreditation workshop in Mozambique.

workshop. Trainees were encouraged to develop laboratory improvement projects that used the skills learned during the workshop while also addressing one or more weaknesses identified during the baseline audit. Defined laboratory improvement projects were implemented during the 3-month intervals between workshops (Figure 1). Mentorship was provided to each laboratory to support staff to incorporate new skills and implement improvement projects. The approach to mentorship in Mozambique was for the mentor to reside in the laboratory for 8 weeks and then leave the laboratory for a subsequent 8 weeks. This schedule was repeated 3 times, such that each laboratory benefited from 24 weeks of mentorship during the SLMTA program (January 2011–April 2012). Mentorship was provided by expatriate mentors. The mentor's role was to assist the laboratory staff in developing and implementing their action plans for improvement projects, to mentor the laboratory manager and quality manager to improve their ability to analyze and use data to advocate for the laboratory needs, to improve communication skills of all staff, and in some cases, to host weekly seminars to build on skills taught in the most recent SLMTA workshop and expand the access to this knowledge to other laboratory staff who were not participating in the SLMTA workshops. Mentors were not to act as the quality manager or to be seen as the person responsible for implementing QMS. PPP volunteers did not provide mentorship to laboratory staff at the facility level but instead focused on building the capacity of MOH staff at the national level. Upon completion of all 3 SLMTA workshops, final audits were conducted by teams constituted by MOH auditors, as well as by PPP volunteer auditors and other expert auditors. No MOH auditor could audit a laboratory where they also worked.

RESULTS

Advocacy for Implementing a Standardized and Systematic Laboratory Quality Improvement Program

The PPP provided a forum to introduce and promote the importance of institutionalizing a national laboratory quality improvement program to MOH leadership and provided the initial data that were needed to gain buy-in from MOH

leadership to commit to this program. PPP volunteers piloted the checklist in 3 MOH laboratories as a means to demonstrate the utility of the data to identify strengths and weaknesses in the laboratory's quality systems and prioritize interventions for improvement. Data from pilot assessments are not shown in this report as they were used solely to advocate for the adoption of a stepwise approach to laboratory quality improvement and were not considered baseline audit scores for any of the laboratories.

Training to Develop Local Capacity for NLQA Program Implementation

PPP volunteers trained 18 MOH laboratory staff to conduct audits by using the SLIPTA checklist. The auditor training curriculum was developed and delivered by PPP volunteers and was based on ISO 15 189 and the SLIPTA checklist. Trainings included both theory and practice, whereby theoretical concepts were tested in practice through mock audits in clinical laboratories, using the SLIPTA checklist and guidance from experienced PPP volunteers. Trainings also included communication of audit results to stakeholders. The importance of immediate feedback following an audit was stressed. All trainees were objectively evaluated by the PPP volunteers, and recommendations were made to the MOH of those who should be considered for further development as national level auditors.

PPP volunteers delivered project management training to 28 trainees to improve the capacity of MOH staff to manage the large amounts of data coming from the SLIPTA checklist, to organize workshop logistics, and to ensure that tasks required for successful implementation of the program are tracked and accounted for. PPP volunteers were not certified SLMTA trainers and thus did not facilitate SLMTA trainings. SLMTA facilitation was led by other PEPFAR implementing partners.

SLIPTA Implementation

Baseline and final audits were conducted by teams of newly trained MOH auditors alongside PPP expert auditors in the 6 laboratories selected by the MOH to participate in round 1. In some cases, expert auditors from the CDC or other implementing partner organizations participated. The laboratories included 2 central hospital laboratories in Beira and Nampula and 4 national reference laboratories (microbiology, serology, immunology, and tuberculosis). Baseline audits were conducted between January and February 2011. The first SLMTA workshop took place during the week of 21 February 2011, with the second taking place during the week of 6 June and the final workshop taking place during the week of 17 October. Final audits were conducted from 26 March to 6 April 2012 (Figure 1).

Baseline and final audits scores are illustrated in Figure 2. No laboratories achieved 1 star at baseline, although 2 laboratories were close (14 points from 1 star). At the end of the program, 3 laboratories had achieved 1 star (the National Microbiology Reference Laboratory, the Nampula Central Hospital Laboratory, and the National Serology Reference Laboratory), the

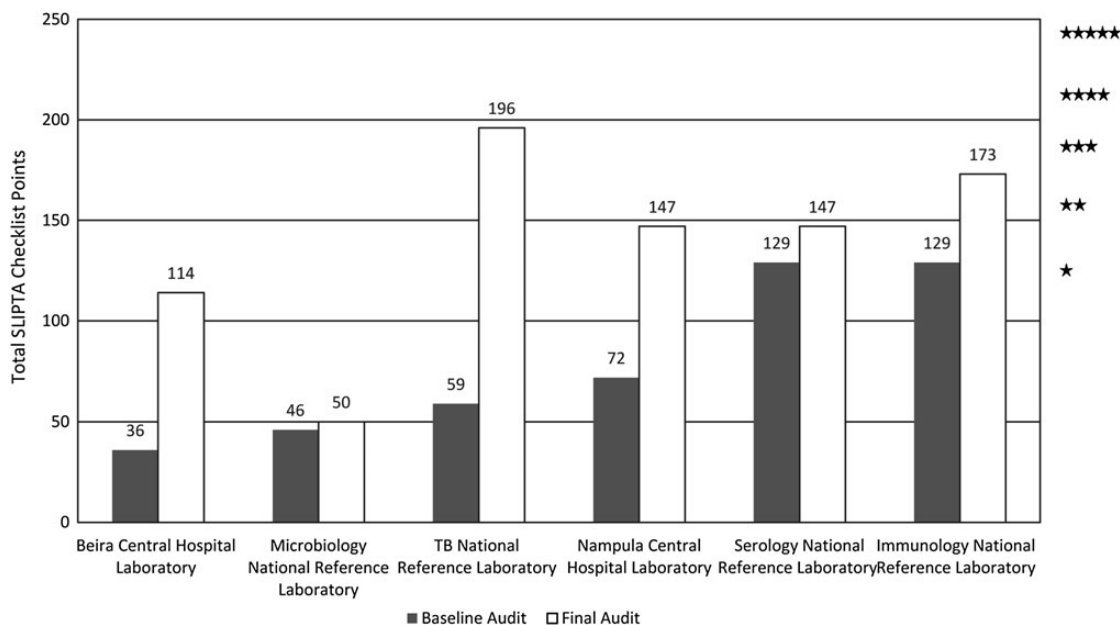


Figure 2. Baseline and final audit results for 6 laboratories enrolled in the Strengthening Laboratory Management Towards Accreditation workshop in Mozambique.

National Immunology Reference Laboratory had achieved 2 stars, and the National Tuberculosis Reference Laboratory had achieved 3 stars. Among the 4 laboratories demonstrating most marked improvement, baseline checklist scores were low (<30% of total points), and improvement projects implemented over the 15-month period focused on correcting deficiencies that were within the control of the laboratory management and staff and did not require significant financial investment nor changes in national policies and laws that are outside the control of the laboratory staff. In contrast, the 2 laboratories with higher baseline checklist scores (serology and immunology) had fewer areas that could be improved without significant investments in infrastructure improvements (to address facility and safety deficiencies) or changes in national policies, such as purchasing, vendor qualification, warehousing, and distribution.

DISCUSSION

SLIPTA and SLMTA tools act synergistically to improve the quality of laboratory processes, with a focus on 13 quality essentials. Currently, approximately 617 laboratories in 47 countries are enrolled in the SLMTA to improve the quality management of laboratories [11]. In addition, 164 laboratories in 18 countries were audited by African Society for Laboratory Medicine (ASLM) auditors, using the SLIPTA checklist (Talkmore Martuta, personal communication, 2015). These laboratories were awarded and issued a certificate of star recognition (1–5 stars) by the secretariat of the ASLM [12]. These tools and processes are intended to encourage, support, and recognize implementation of QMS in medical laboratories.

The adoption and implementation of these tools in Mozambique was initiated as a result of the PPP efforts during 2010–2012, which demonstrated the value of using a standardized and quantitative checklist to evaluate the place along the continuum of QMS implementation where a given laboratory is. The MOH had embraced their mandate to deliver a quality laboratory service to the population but had not yet formally adopted a strategy nor invested in establishing a national laboratory quality unit within the MOH. The results of the pilot audits conducted and presented to the MOH by the PPP volunteers was a critical turning point for the MOH to buy into the SLIPTA process. This demonstrates that data-supported advocacy is an important step to building MOH commitment. Sustainability of the NLQA program was prioritized at every stage of the planning for roll out of the NLQA program. Including auditor training of MOH staff as a first step demonstrated early on that building local capacity to implement the program would reduce costs to the MOH and build commitment among MOH staff to the national program. The results from the first cohort of laboratories were encouraging because all laboratories improved their checklist scores from baseline to final audits. Interestingly, the degree of improvement ranged widely among the laboratories, from a <1-fold increase to a >3-fold increase in scores. The most obvious reason for these differences, despite all laboratory staff receiving the same training, mentorship, and supervision, is that all laboratories were not starting from the same place with regard to their understanding and implementation of QMS nor to the conditions of their laboratory and equipment. The serology and immunology national reference laboratories showed the least dramatic improvement from baseline to final

audit but also had the highest baseline audit scores. This is likely because these 2 laboratories had been targeted by a number of interventions over the years, by the WHO and PEPFAR. The serology laboratory serves as the WHO reference laboratory for measles testing and became the human immunodeficiency virus (HIV) reference laboratory with intense investments by the PEPFAR in infrastructure, equipment, and staff development. The immunology laboratory also benefited from consistent PEPFAR support, as the laboratory serves as the national reference laboratory for CD4⁺ T-cell count testing for the country's HIV care and treatment program. The tuberculosis reference laboratory made the greatest improvement and managed to reach a 3 star level, as determined by the final audit score. This laboratory was recently renovated, including new equipment, and thus was able to meet checklist requirements for equipment, facility, and safety to a greater degree than the other laboratories in the cohort. Furthermore, the investment in infrastructure and equipment was a motivating factor for staff. Staff morale is an important aspect of QMS implementation to be considered. Given low salaries and relatively poor working conditions in many public sector laboratories in Africa, asking staff to add additional QMS duties is always met with resistance. Even small investment in these laboratories by government and partners sends a positive message to laboratory staff that their work matters and increases willingness and desire to contribute to quality improvement.

The benefits of the PPP in Mozambique were 2-fold. First, it provided the momentum and advocacy needed for the MOH to commit to establishing a NLQA program and adopt the SLIPTA checklist and SLMTA curriculum. Data from the pilot audits done by PPP volunteers demonstrated the value that quantitative and objective data can bring to highlight deficiencies in laboratory quality processes and target corrective action investments. The PPP also provided the opportunity to introduce MOH leadership to the concepts of QMS and to create enthusiasm and commitment to invest time and resources into establishing a NLQA program. Second, PPP volunteers provided training in the native Portuguese language, which established competencies for laboratory auditing and project management. Establishing a cadre of MOH personnel who could support implementation and monitoring of the NLQA program meant that Mozambique had the capacity to institutionalize their program from the very beginning. This is in contrast to other African countries, where the implementation and management of the SLIPTA program is done by PEPFAR implementing partners or other donors, with minimal leadership by the host country (personnel observation).

In Mozambique, the focus of the PPP was distinct from that of the PEPFAR implementing partners. The PPP was focused on supporting the MOH staff assigned to the quality assurance unit and responsible for the management of the NLQA program (eg, promoting institutionalization of the program), while

implementing partners focused on facility-level technical assistance and SLMTA facilitation. However, all partners, including the PPP, shared the same vision and message: institutionalization of the NLQA program was the only pathway to sustainability.

The PPP was limited by the nature of the agreement with the PEPFAR in its ability to directly finance workshops, pay travel and per diems of MOH trainees, and directly purchase materials for workshops or laboratory improvement projects. In these cases, the implementing partners had the budgets and mechanisms to support the roll out of the NLQA program and, in so doing, complimented what the PPP was bringing to the initiative. A key advantage of the PPP in Mozambique was Becton Dickinson's ability to access certified quality managers from their operations in Brazil. This meant that volunteers selected to work in Mozambique were native Portuguese speakers with current and relevant QMS experience, as well as experience working in resource-limited settings. The distinction between the business operations of Becton Dickinson and the PPP operations was extremely clear and well articulated in all documentation presented to the MOH during initial meetings. Over the course of the PPP engagement in Mozambique, no conflict of interest occurred.

The path this pioneering partnership paved for the rest of the laboratories in the nation is important. As a result of the PPP, Mozambique now has a NLQA unit at the ministerial level, expertise to do in-house audits, and experience and tools to assess the state of the laboratory network in the national language. Mozambique has shared their experience and Portuguese translations of the SLMTA curriculum and SLIPTA checklist with other Lusophone countries and has been invited by the Angolan MOH to support the roll out of the Angolan laboratory quality improvement program. Because the PPP had invested in training and mentoring a cadre of local auditors, the MOH was well positioned to take ownership of their NLQA program and lead its implementation with technical support from the CDC and implementing partners. As of August 2013, the MOH decentralized the NLQA program to the provincial level, training and empowering provincial laboratory supervisors to lead the implementation of SLMTA in their provinces. This approach has significantly increased the reach of the program while keeping costs manageable. Sufficient numbers of trained human resources are required for this approach to be successful and sustainable. The goals of the PPP to develop the local capacity to lead and manage Mozambique's NLQA program were achieved and Mozambican auditors and program managers are now available to support the growing NLQA program in Mozambique.

Quality-assured laboratory services are essential to guarantee accurate patient diagnoses and timely detection of disease threats. International laboratory standards provide the target toward which laboratory quality improvement efforts aim. Through the PPP, advocacy, education, and measurable improvements in laboratory quality were accelerated in Mozambique. Development and empowerment of MOH laboratory managers and leaders

were prioritized to promote institutionalization of the program and country ownership. Taken together, the PPP provided the technical support and momentum to launch the NLQA program in Mozambique. With local capacity and country ownership, the program continues to expand its reach to increasing numbers of laboratories across the tiered laboratory network. Mozambique represents a model of program sustainability in the region.

Notes

Disclaimer. The comments and conclusions in this report are those of the authors and do not necessarily represent the official position of the Department of Health and Human Services, the Public Health Service, or the Centers for Disease Control and Prevention (CDC). The use of trade names is for identification only and does not constitute endorsement by the Department of Health and Human Services, the Public Health Service, or the CDC.

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